



# CHANGES TO 42 C.F.R. PART 2

42 CFR PART 2 FINAL RULE PUBLISHED 7/15/2020

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# SUMMARY OF JULY 2020 FINAL RULE

- Definitions (§ 2.11)
- Amends the definition of “Records” to create an exception so that information conveyed orally by a Part 2 program to a non-Part 2 provider for treatment purposes with consent does not become a “record” subject to Part 2 merely because it is reduced to writing by that non-Part 2 provider
- Applicability (§ 2.12)
- Provides that the recording of information about an SUD and its treatment by a non-Part 2 provider does not render a medical record subject to Part 2, provided that the non-Part 2 provider segments or holds a part any Part 2 patient record previously received

# SUMMARY OF JULY 2020 FINAL RULE

- Consent requirements (§ 2.31)
  - Permits patients to consent to the disclosure of their information for operations purposes to certain entities without naming a specific individual and includes special instructions for health information exchanges (HIEs) and research institutions
  - For disclosures to HIEs and research institutions a consent must still include both the name(s) of the entity(-ies) and –
    - 1. The name(s) of individual or entity participant(s); or
    - 2. A general designation of an individual or entity participant(s) or class of participants that must be limited to a participant(s) who has a treating provider relationship with the patient whose information is being disclosed.
- Prohibition on redisclosure (§ 2.32)
  - Clarifies that non-Part 2 providers do not need to redact information in their or another non-Part 2 record and confirms that redisclosure is permitted if expressly permitted by written consent of the patient or permitted under Part 2 regulations

# SUMMARY OF JULY 2020 FINAL RULE

- Disclosures permitted with written consent (§ 2.33)
  - Allows disclosure to specified entities and individuals for purposes of payment and certain health care operational activities, including care coordination and case management
- Disclosures to prevent multiple enrollments (§ 2.34)
  - Permits non-opioid treatment providers (Non-OTPs) with a treating provider relationship to access central registries
- Disclosures to Prescription Drug Monitoring Programs (§ 2.36)
  - Permits opioid treatment programs (OTPs) to disclose dispensing and prescribing data, as required by applicable state law, to prescription drug monitoring programs (PDMP), subject to patient consent
- Medical Emergencies (§ 2.51)
  - Authorizes disclosure of SUD records to another Part 2 program or other SUD treatment provider during declared emergencies resulting from natural disasters

# SUMMARY OF JULY 2020 FINAL RULE

- Research (§ 2.52)
  - Permits research disclosures of Part 2 data by a HIPAA covered entity or business associate to individuals and organizations who are not HIPAA covered entities or subject to the Common Rule
- Audit and evaluation (§ 2.53)
  - Clarifies specific situations that fall within the scope of permissible disclosures for audits and program evaluation purposes such that federal, state and local governmental agencies and third-party payors may conduct audits and evaluations to identify actions necessary to improve care; that audits and evaluations may include medical necessity and utilization reviews; and that auditors may include quality assurance organizations as well as entities with direct administrative control over a Part 2 program or a lawful holder
- Orders authorizing use of undercover agents and informants (§ 2.67)
  - Amends the period for court-ordered placement of an undercover agent and informant within a Part 2 program to 12 months unless extended by a new court order

# 42 C.F.R. PART 2: CARES Act Modifications to 42 U.S.C. § 290dd-2

- CARES Act (Coronavirus Aid, Relief, and Economic Security Act) amended the federal statute on which Part 2 is based
- The Part 2 regulations were not directly amended by the CARES Act
- HHS indicated that final regulations that incorporate the CARES Act revisions will not be effective prior to March 2021



# SOURCES AND ADDITIONAL RESOURCES

- American Society of Addiction Medicine: [https://www.asam.org/42 CFR Part 2 webpage](https://www.asam.org/42-CFR-Part-2-webpage)
- Substance Abuse and Mental Health Services Administration: <https://www.samhsa.gov/>
- HHS Fact Sheet on Final Rule Changes: <https://www.hhs.gov/about/news/2020/07/13/fact-sheet-samhsa-42-cfr-part-2-revised-rule.html>
- Federal Register Link to Final Published Rule: <https://www.federalregister.gov/documents/2020/07/15/2020-14675/confidentiality-of-substance-use-disorder-patient-records>